

KRISTINE E. JOHNSON (7190)  
JULIETTE P. WHITE (9616)  
PARSONS BEHLE & LATIMER  
201 South Main Street, Suite 1800  
Salt Lake City, Utah 84111  
Telephone: 801.532.1234  
Facsimile: 801.536.6111  
[ecf@parsonbehle.com](mailto:ecf@parsonbehle.com)  
*Attorneys for Plaintiffs*

**IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF UTAH, CENTRAL DIVISION**

THORNE RESEARCH, INC. and SOFTGEL FORMULATORS, INC.,  Plaintiffs,  vs.  ATLANTIC PRO-NUTRIENTS, INC. d/b/a/ XYMOGEN,  Defendant	Case No. 2:13-cv-00784  Judge Ted Stewart  <b>PLAINTIFFS' MOTION FOR CLAIM CONSTRUCTION AND MEMORANDUM IN SUPPORT</b>
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Pursuant to the Court's Scheduling Order and L.P.R. 4.2, Plaintiffs Thorne Research, Inc. ("Thorne") and Softgel Formulators, Inc. ("SFI"), (collectively, "Thorne") submit their Motion for Claim Construction and Memorandum in Support.

**INTRODUCTION & STATEMENT REGARDING IMPLICATIONS OF CLAIM  
CONSTRUCTION**

This case involves claims of infringement of a patent owned by Plaintiff Softgel Formulators, Inc., and exclusively licensed to Thorne Research, Inc. The patent at issue, United States Patent No. 8,491,888 (the "'888 patent") issued on July 23, 2013. It pertains generally to a composition for a crystal-free, absorbable coenzyme Q10 (CoQ10). CoQ10 is a substance manufactured by the human body. It has a number of uses, including the use by human cells to produce energy the body requires for cell growth and maintenance. It is frequently sold in the

United States as a nutritional supplement, as CoQ10 levels decrease with age and may be low in people with certain diseases or disorders.

The patented invention, in particular, relates to a CoQ10 composition that is not only crystal free, but also is highly bioavailable and absorbable. Bioavailability generally refers to the proportion of the administered substance (here, CoQ10) that is capable of being absorbed and available for use and storage by the human body. The claimed composition also includes a solvent and a carrier oil, which oil acts as a transporter for the CoQ10 as it is absorbed into the body.

Thorne is requesting that the Court construe only two terms from the '888 patent: "non-crystalline" and "carrier oil." As discussed herein, both of those terms are used in the patents-in-suit in a very specific manner which requires a proper claim construction considering the patent specification. Thorne's proposed constructions are consistent with, and supported by, the pertinent intrinsic evidence and should be adopted.

Regarding the application of L.P.R. 6.2, providing that motions for partial summary judgment on an issue upon which "construction of a term may be dispositive" should be filed at the same time as motions for claim construction, at this point in time and given the information produced by Defendant in discovery, Thorne does not believe that construction of either of the terms it proposes are dispositive of the issue of infringement or patent validity. Furthermore, Thorne notes that Defendant has declined to serve non-infringement contentions pursuant to L.P.R. 2.4 and 3.2, and accordingly Thorne does not believe that infringement of the '888 patent is a disputed issue. Thorne reserves the right to bring a motion for summary judgment pursuant to L.P.R. 6.2 should Defendant be permitted to advance an argument indicating that construction of these terms may be dispositive of the issue of infringement.

## **ARGUMENT**

### **I. Applicable General Law of Claim Construction.**

The claim construction process is well known by this Court and requires little explication. In claim construction, a court examines the “intrinsic evidence,” which is “the words of the claims themselves, the remainder of the [patent] specification, [and] the prosecution history.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314, 1317 (Fed. Cir. 2005). “[T]he claims” are typically ascribed their “ordinary and customary meaning” and “the context in which a term is used in the asserted claim can be highly instructive.” *Id.* at 1314.

“[T]he specification ‘is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.’” *Id.* at 1315. “The construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Id.*

Courts “should also consider the patent’s prosecution history.” *Id.* at 1317. It “often inform[s] the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution.” *Id.*

Courts also may consider “extrinsic” evidence, including dictionaries and publications in the relevant field “if the court deems it helpful in determining ‘the true meaning of language used in the patent claims.’” *Id.* at 1317-19. Expert testimony can also be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* at 1318.

### **II. The Terms “Non-Crystalline” and “Carrier Oil” Contained in the ‘888 Patent Should Be Construed as Proposed by Thorne.**

Thorne asserts infringement of Claims 1-5 and 11-15 of the '888 patent. The term “non-crystalline” appears in claims 1 and 14 and the term “carrier oil” appears in claims 1, 14, and 15.

Specifically, Claim 1 provides, in pertinent part:

A crystal-free coenzyme Q10 composition comprising:  
*non-crystalline* coenzyme Q10 present in an amount of 5.3% by weight to about 12% by weight based on the total weight of the composition; ... and  
a *carrier oil*.

(Emphasis added).

Similarly, claim 14 provides, in pertinent part:

A crystal-free coenzyme Q10 composition comprising:  
an amount of 5.3% by weight to about 12% by weight *non-crystalline* coenzyme Q10; ... and  
24-34% by weight *carrier oil*.

(Emphasis added).

Claim 15 depends from claim 14 and provides, in pertinent part:

The crystal-free coenzyme Q10 composition of claim 14 wherein: ...  
the *carrier oil* is selected from the group consisting of flax seed oil, soy lipids, borage lipids, marine lipids and combinations thereof.

(Emphasis added).

A. “Non-Crystalline,” Correctly Construed in Accordance with the Intrinsic Evidence, Means “Lacking Crystals Visible by Light Microscope at Magnifications of 640x.”

Properly construed, “non-crystalline,” as used in claims 1 and 14 means “lacking crystals visible by light microscope at magnifications of 640x.” The proposed construction is derived from the '888 patent, which states that the “present invention relates to a crystal-free absorbable CoQ10 [meaning “coenzyme Q10”] wherein no CoQ10 crystals are visible by light microscope at magnifications of 640x.” Col. 2, lines 30-33.

The '888 patent goes on to state that “CoQ10 for the purpose of supplementation is produced in its pure, crystal form by various manufacturing methods.” Col. 1, lines 33-35. It describes methods of making a CoQ10 composition that involve mixing the crystal CoQ10,

solvent, and carrier oil and dissolving the CoQ10 into the solvent. The crystal CoQ10 may be melted and added to the solvent and carrier oil. The described test method will permit verification of whether the manufacturing method puts the starting crystal CoQ10 into a non-crystalline form. *See* col. 4, lines 11-24.

Furthermore, a determination of whether a material possesses some particular physical property necessarily includes reliance on test equipment and/or comparison to a recognized standard. The '888 patent expressly sets forth the test method to be used in determining whether CoQ10 in a composition appears in the claimed non-crystalline form. It follows that the meaning of "non-crystalline" thus must be linked to the test method described in the patent.

Any effort to determine whether CoQ10 is non-crystalline will certainly include some sort of detection limit inherent in the test equipment selected. Instead of allowing some unknown detection limit of some unnamed test equipment to determine whether CoQ10 is non-crystalline, the '888 patent facilitates certainty in the scope of protection claimed by specifying both the equipment (light microscope) and the detection limit (visible at 640x). Accordingly, "non-crystalline" should be construed to mean "lacking crystals visible by light microscope at magnifications of 640x." Any other construction would impermissibly imbue the patent scope with uncertainty.

- B. “Carrier Oil” Correctly Construed in Keeping with the Intrinsic Evidence, Means “An Oil That Increases the Volume of an Individual Dosage of CoQ10 Delivered into the Intestines of the Human Taking the Present Invention, Which Increases the Overall Surface Area from Which the CoQ10 Can be Absorbed.”

Properly construed, “carrier oil,” as used in claims 1, 14, and 15 means “an oil that increases the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed.” The proposed construction is taken directly from the ‘888 patent, which similarly states that the “lipid carrier increases the volume of an individual dosage of CoQ10 delivered into the intestines of the human taking the present invention, which increases the overall surface area from which the CoQ10 can be absorbed.” Col. 3, lines 4-9.

While the referenced text mentions “lipid carrier” instead of “carrier oil,” the other sentences of the same paragraph demonstrate that the description of the *lipid carrier* in the ‘888 patent is intended to define properties of the *carrier oil*. The first sentence begins “The carrier oil of the present invention aids in improving ....”. The second sentence begins “The carrier oil acts as a transporter ....”. The third sentence contains the initial reference to lipid carrier. The fourth sentence is quoted in the proposed construction, and the fifth through seventh sentences return to use of “carrier oil,” specifically naming soy lipids, borage lipids, and marine lipids as examples of the carrier oil. It thus is apparent that “lipid carrier” and “carrier oil” refer to the same ingredient of the claimed composition.

Furthermore, the paragraph discussed above enumerates several properties of “carrier oil.” The first through third sentences describe carrier oil properties with respect to body functions, *i.e.*, “aids in improving absorption,” “acts as a transporter ... across the absorption cells,” and “cannot be absorbed” without. The fifth through seventh sentences list examples of

carrier oils. However, the fourth sentence referenced for construction uniquely describes the carrier oil's *effect* on the CoQ10 composition; namely, increasing volume (which increases covered surface area.) Since claims 1, 14, and 15 are claims to a composition, the fourth sentence thus represents the most appropriate disclosure for understanding the meaning of "carrier oil" in that context of a composition claim; *i.e.*, construing the claim which reference to that substance's effect on the composition.

Relying on the first through third sentences to construe "carrier oil" would involve evaluating allegedly infringing compositions primarily based upon their effect on the body. Requiring a determination of an ingredient's effect on humans would unnecessarily complicate a determination of the scope of the patent. Instead, relying on the fourth sentence permits an evaluation of an allegedly infringing composition based on the nature of the ingredients themselves. Even though the fourth sentence refers to CoQ10 being absorbed, the reference is solely in the context of modifying the nature of the increased "volume of an individual dosage." That is, the increased dosage volume is of a nature that increases surface area for CoQ10 absorption. No determination of a human effect is required. Accordingly, "carrier oil" should be construed as proposed by Thorne.

DATED this 15th day of May, 2015.

PARSONS BEHLE & LATIMER

/s/ Kristine E. Johnson

KRISTINE E. JOHNSON

JULIETTE P. WHITE

*Attorneys for Plaintiffs*

CERTIFICATE OF SERVICE

**I HEREBY CERTIFY** that on the 15th day of May, 2015, I caused the foregoing document to be filed via ECF which provided electronic notice to all counsel of record.

/s/ Kristine E. Johnson  
Kristine E. Johnson